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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/065,161      | 09/23/2002  | James Feine          | USI-36              | 4873             |

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| EXAMINER |
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BUMGARNER, MELBA N

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| ART UNIT | PAPER NUMBER |
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3732

DATE MAILED: 05/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/065,161

Applicant(s)

FEINE, JAMES

Examiner

Melba Bumgarner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Objections*

1. Claims 2, 20, and 21 are objected to because of the following informalities: recitation of “the polymer” lacks sufficient antecedent basis. Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-13, 20, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Currie (5,178,537). Currie discloses a pre-sterilized, disposable tip individually packaged comprising a monolithic polymeric dental tip 14 having a coupling element 22 at a proximal end; a sealed container individually packaging the tip, wherein the tip is sterilizable in the container (column 2 line 38, figure 4). Patentable weight is not given to the intended use of the dental tip, however, it is noted that the coupling element is capable of attachment to an ultrasonic dental insert. As to claim 2, the polymer is nylon (column 2 line 25). As to claims 3-5, patentable weight is not given to the process by which the packaged tip is made because a product claim is properly met if the final product is shown regardless of the process used. However, Currie shows the tip is molded (column 5 line 51) and the sealed container sterilized by gas permeation or irradiation (column 4 line 65). As to claim 6, the coupling element comprises threads (figure 2). As to claim 7, the container comprises paper (column 4 line 39). As to claim 8, the container comprises polymeric film (column 4 line 37). As to claim 10, Currie shows a method for

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supplying a sterilized, single-use, disposable tip comprising forming a polymeric tip, individually packaging the tip in a sealed container, and sterilizing the packaged tip. As to claim 11, the method shows coupling the packaged tip with other tips and packaging the coupled tips as a quantity package. As to claims 12 and 13, the distribution of the tips in bulk or individually is inherently shown in the method of Currie. As to claim 20, the polymer, such as nylon 6, deforms at autoclave conditions.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 10-19 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Himeno et al. (5,899,693) in view of Currie. Himeno et al. discloses a method of using a disposable tip with an ultrasonic dental scaler comprising attaching the monolithic plastic ultrasonic dental scalar tip 2 to a dental insert B, securing the dental insert in a handpiece C of a dental scaler, operating the scaler to clean dental implants (column 1 line 25), and disposing the tip after use (column 3 line 11). However, Himeno et al. do not show supplying a sterilized polymeric tip. Currie teaches method steps forming a polymeric tip, individually packaging the tip in a sealed container, sterilizing the packaged tip, and removing the tip from the container. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Himeno et al. to include the steps of supplying the tip as in Currie. One would be motivated to make such a modification to have tip that is inexpensive, easy to attach,

and minimizes the risk of infection or disease in view of Currie. The step of transporting the sealed container to a dental office is inherently performed in using the tip. It would have been an obvious matter of choice to one of ordinary skill in the art as to the known material of the dental implant. Use of titanium implant is not critical to the claimed methods. As to claim 14, it is would have been an obvious matter of choice to one of ordinary skill in the art as to the sealing of the container as the specification states that “[a]ny of a variety of packaging methods can be employed”. As to claim 19, it would have been an obvious matter of choice to one of ordinary skill in the art to sterilize the dental insert and repeat the steps with a different patient, since it is known in the art that inserts are sterilized after each patient and the dental practitioner performs the dental treatment on a recurring basis.

6. Claims 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Currie in view of Manzoli (6,302,691). Currie discloses a tip that shows the limitations as described above; however, Currie does not show the polymer changes color at autoclave conditions.

Manzoli teaches a dental tool comprising a polymer including a dye that changes color at autoclave conditions (column 3 line 63). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the tip of Currie to have the dye of Manzoli in order to have a visual indicator showing the sterilization that has occurred to the tip.

7. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Himeno et al. in view of Currie and further in view of Manzoli. The modified tip of Himeno et al. and Currie discloses a tip that shows the limitations as described above; however, they do not show the polymer changes color at autoclave conditions. Manzoli teaches a dental tool comprising a polymer including a dye that changes color at autoclave conditions (column 3 line 63). It would

have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the tip to have the dye of Manzoli in order to have a visual indicator showing the sterilization that has occurred to the tip.

### *Response to Arguments*

8. Applicant's arguments filed December 8, 2004 have been fully considered but they are not persuasive. In response to applicant's argument that the Currie reference fails to teach a tip for use with an ultrasonic dental insert, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). In response to applicant's argument that the Himeno et al. reference show a different position and mode of attachment of the tip to the ultrasonic device is irrelevant to the claimed limitations.

### *Conclusion*

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melba Bumgarner whose telephone number is 571-272-4709. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at 571-272-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Melba Bumgarner  
Primary Examiner